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Research Article

Fast Dissolving Oral Strips: An Approach for the Delivery of Ondansetron

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Abstract

Fast dissolving oral strips provide a more convenient and patient-friendly alternative to conventional oral dosage forms for those patients having difficulty in swallowing tablets/capsules etc. strips uses a water-dispersing polymer to boost the drug's bioavailability as it release straight into the bloodstream without the liver having to digest it first. Administering Ondansetron hydrochloride via fast dissolving strips has a number of benefits, including increased patient compliance and improved therapeutic efficacy due to the drug's quick absorption from the highly vascularized oral mucosa, which prevents first-pass metabolism. The antiemetic medication Ondansetron, an antagonist for serotonin receptor type 5 (SERT5), is useful in managing nausea and vomiting brought on by chemotherapy for cancer. Only 60–70% of its limited oral bioavailability may be attributed to first-pass metabolism. Ondansetron has a half-life of three to five hours and is readily soluble in water, making this route of administration appropriate. The goal of this study is to formulate Ondansetron as fast dissolving oral strip intended for instant release in an effort to maximize its therapeutic impact.

Keywords: Ondansetron, fast dissolving, strip, antiemetic.

INTRODUCTION

A novel drug administration method called a fast-dissolving strip was developed using transdermal patch technology to better administer drugs orally. Different trans-mucosal routes have been established to deliver therapeutic medicines. These routes store the therapeutic agent at a particular region of action. Fast-dissolving strips have gained popularity as a novel drug delivery system due to their ease of administration and rapid onset of action. When taken sublingually, these films allow for swift drug absorption through the thin, permeable membrane of the sublingual mucosa, which is richly perfused with blood vessels. This leads to instant bioavailability and a quick onset of therapeutic effects.[1,2]

A selective 5-HT3 receptor antagonist ondansetron is used to prevent nausea and vomiting caused by radiation therapy, chemotherapy, and surgery in cancer patients. Ondansetron is available on the market in authorized intramuscular, intravenous, and oral forms.[3,4] Administering medication intramuscularly may be uncomfortable and increase the risk of bleeding, abscess development, and infection. Common obstacles to intravenous medicine delivery included phlebitis, infiltration, extravasation, and infections. Conventional oral formulations may not be self-administered by patients who have difficulty swallowing pills.[5]

This study aims to create fast-dissolving strips containing ondansetron. The goal is to enhance the drug's bioavailability and provide a convenient, dry dosage form that optimizes its therapeutic efficacy. By achieving rapid dissolution and absorption, these films may offer improved patient outcomes and a more effective treatment experience.

Some potential benefits of fast-dissolving strips include:

1. Improved bioavailability: Rapid absorption and increased bioavailability may lead to enhanced therapeutic effects.

2. Convenient administration: Dry dosage forms can be easier to administer, especially for patients with difficulty swallowing or nausea.

3. Optimized therapeutic effect: By achieving rapid and consistent drug absorption, these films may provide more effective relief from nausea and vomiting.[6,7]

MATERIALS AND METHODOLOGY

MATERIAL

Ondansetron HCL, HPMC K4M, HPMC E50, PEG 400, citric acid and Sodium saccharine were obtained from CDH, Delhi and of analytical grade.

METHODOLOGY

Pre formulation Studies

Pre-formulation is the study of a drug's chemical and physical characteristics, both alone and in conjunction with excipients. Utilizing pre-formulation factors increases the likelihood of creating a product that is palatable, secure, effective, and stable.

Organoleptic properties

The API's sensory properties including color, taste, and odor, was evaluated.

Melting Point

Melting point was obtained by use of melting point apparatus. The three values were recorded and mean was taken.

FT- IR Studies

A technique known as infrared spectrum matching was used to identify the chemical. This sample weighed around 100 mg, and it was crushed using a hydraulic press set to 10 tons of pressure to create a translucent pellet. It was examined using a Shimadzu FT-IR spectrophotometer between 4000-5000 cm1. The sample's infrared spectrum was compared to that of pure medication, and peak presence or absence was identified by matching.

Calibration Curve of Ondansetron HCl

Standard Stock Solution:

A standard stock solution of ondansetron HCl was prepared by dissolving 100 mg of the drug in 100 ml of 0.1N HCl. A 5 ml aliquot was then diluted to 100 ml to obtain a solution with a concentration of 50 µg/ml.

Determination of λmax:

The λmax was determined by scanning a diluted solution (5µg/ml) from 200-400 nm using a UV spectrophotometer. The maximum absorbance was found at 249 nm.

Calibration Curve:

A calibration curve was constructed by preparing solutions with concentrations ranging from 2-14 µg/ml using 0.1N HCl as the medium. The absorbance of each solution was measured at 249 nm, and a plot of concentration vs. absorbance was generated. The correlation coefficient (R2) was calculated to evaluate the linearity of the curve.[8]

Solubility

Saturated solution of drug was prepared in different solvents and solubility was assessed at room temperature.

Fabrication Method

Distilled water was used to dissolve the water-soluble polymers and plasticizers. After 2 hours of stirring with the magnetic stirrer, the solution was set aside to release any remaining air bubbles. After 30 minutes of careful stirring, the excipients and drug have been completely dissolved and are ready to be combined. At last, a film of the solution was cast onto a suitable petri plate and left for 24 hrs. The dried strip was gently separated from glass plate and cut into a desired size (4 cm^2).[9,10]

Table 1: Composition of Strip

Ingredients (g)	F1	F2	F3	F4	F5
Ondansetron Hydrochloride	0.625	0.625	0.625	0.625	0.625
HPMC E 50	1	1.5	2	-	2.5
HPMC K4M	2	3	4	5	-
PEG 400	8	8	8	8	8
Citric Acid	1	1	1	1	1
Sodium Saccharin	1	1	1	1	1
Distilled Water	100 ml	100 ml	100 ml	100 ml	100 ml

EVALUATION OF FABRICATED STRIPS [11,12]

Thickness

The thickness of the strips was measured using a precision instrument, specifically a micrometer screw gauge, to ensure accurate and reliable results. In order to obtain uniformity of strip, the thickness was evaluated on 5 distinct spots.

Weight Variation

Weight variation was assessed by weighing 10 samples of each formulation individually. The average weight was then calculated and presented in Table 3.

Content Uniformity

Dissolved this strip in 100 ml of simulated saliva with a pH of 6.8 (phosphate buffer with NaCl) by continuous shaking for 30 minutes. This ensures the strip dissolves completely, resulting in a homogeneous solution. 10 ml of the above solution was withdrawn. Diluted this 10 ml solution to a final volume of 50 ml using simulated salivary fluid (simulated saliva with pH 6.8) and analyzed using UV spectrophotometer.

Swelling Index

The strip was securely placed on a stainless steel mesh and immersed in a mortar filled with 50 mL of

simulated salivary medium. Weighing occurred every 30 seconds to monitor how the strip absorbed moisture over time. Excess moisture was delicately blotted away with absorbent tissue to ensure precise weight measurements.[13,14]

pH

Taken one film and dissolved it in 5 mL of the phosphate buffer solution. Ensure the film is completely dissolved to ensure accurate pH measurement. pH electrode submerged into the solution. Electrode was allowed to equilibrate for about 1 minute to stabilize the pH reading.

Folding Endurance

The folding endurance test evaluates how many times a strip can be folded at the same spot without breaking. This test helps determine the strip's fragility or flexibility by measuring its ability to endure repeated folding at a single point.[15]

In vitro Dispersion

Dispersion times of the prepared strips were determined. Each individual strip was dropped into a beaker containing 500 ml simulated saliva fluid pH 6.8 at 37C°, and the time required for complete strip disintegration was observed visually and recorded using a stopwatch. [16]

In vitro Release

The process carried out in 500 ml beaker filled with simulated saliva with pH 6.8 in USP paddle apparatus (type II), operating at rotation 50 rpm with dissolution medium at 37.5± 0.5 degree celsius. 5ml from the sample was removed in every 30 seconds and exchanged by 5ml of fresh medium .UV reading obtained and percent drug release measured.[17,18]

Stability Studies

The stability studies are the important parameter which identifies whether the formulation was able to bear any change in temperature. The stability studies were done for 3 months at room temperature [30±2°C], refrigerated condition i.e. [4±2°C] and at accelerated condition [40±20°C, 75% RH] After 1 month, 2 months and 3 months of storage.

RESULT AND DISCUSSION

Preformulation Studies

Organoleptic Properties

It was discovered that ondansetron HCl was a white or nearly white powder with no odor or taste, discernible odor and a bitter taste in the research. In accordance with IP specification, drug exhibited a similar appearance, flavor, and odor.

Melting Point

Melting point was obtained by mean of the three values i.e. 325°C, 326°C, 325°C.This led to a melting point of 325.33°C.

FT-IR Spectrometric Reports

Identity and purity of ondansetron was characterized by FT-IR investigation (SHIMADZU). Figure no. 1 and table no. 2 display the findings.

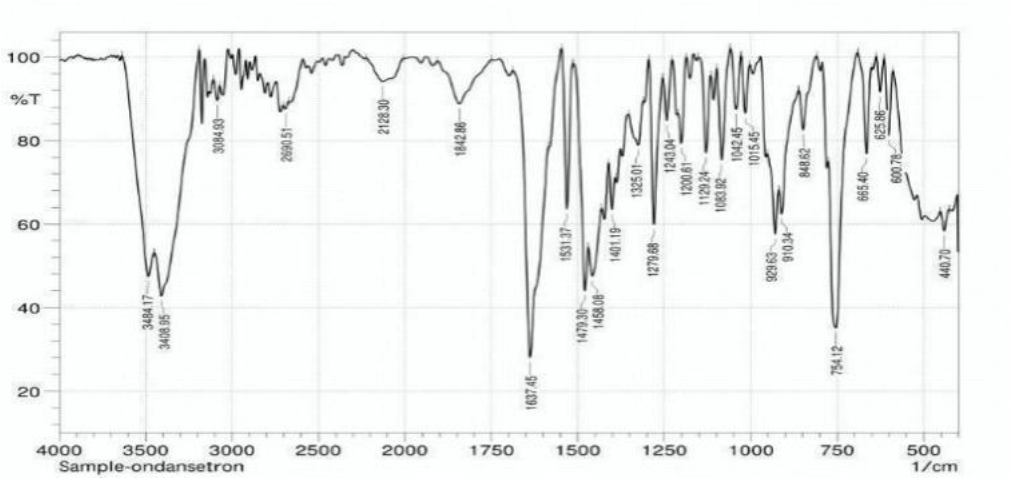

Figure 1: FT-IR Spectrum of Pure Drug

Table 2: FT-IR Spectral Data of Pure Drug

S. N	Wave Number (cm^{-1})	Functional Group
1	3408	Broad band of bonded OH
2	1637	C=O of aryl acids stretching
3	1458	C=N stretching
4	1420	Aromatic C=C stretching

Standard curve

Standard calibration curve of ondansetron hydrochloride plotted between concentration and absorbance.

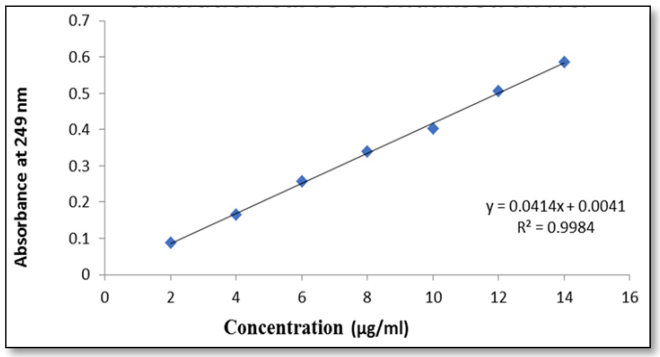

Figure 2: Standard Curve of Ondansetron Hydrochloride

pH Studies

pH readings of 6.5- 6.9 were obtained by the use of a pH meter probe. The findings confirmed the drug was well tolerated in the buccal cavity.

Solubility Test

Studies on the solubility of drugs (APIs) revealed that Ondansetron HCl was sparingly soluble in water and ethanol, soluble in methanol.

EVALUATION TEST RESULTS OF ORAL FILM

Thickness

The strips' overall thickness was consistent. Observations revealed a strip thickness ranging from 0.02+0.49 to 0.12 +0.08mm, with an average value of 0.173 mm. In all cases, calculated standard deviation values are low which indicates that proposed films were uniform in thickness.

Weight Variation

The result indicates that the strip has a uniform weight with a range of 32 to 196 mg. Result is shown in table no. 3.

Folding Endurance

Manually folding the strip repeatedly at a place until they broke was used to determine its folding durability. Even after being folded more than three or four times, the strips showed no signs of damage. This was thus considered the last destination. The results showed that the folding endurance was found to be 221.4+5.41 to 200+3.11. Every strip was determined to have a folding endurance more than 200. All of the strips demonstrated high folding durability, which ensures adequate flexibility, regardless of the polymers utilized.

In vitro dispersion time

Dispersion time (in seconds) for a series of samples was evaluated. The strip dispersed within 40 to 60 seconds in simulated saliva fluid at $37C^0$ showing rapid disintegration and dissolution releasing the API quickly.

Content Uniformity

The content uniformity findings showed that the medication was spread out evenly, with a concentration between 17.79 to 21.23 mg. It was observed from the drug content data that there was no significant difference in uniformity of the drug content.

Swelling Studies

Phosphate buffer solution at pH 6.8 caused the strips to swell. The percentage swelling index of the strips was in between 15.12 to 34.01. Comparative swelling tests across various formulations showed promising results. It was also observed that as the time of contact in water increases, the swelling index was also found to be increased.

TABLE 3: Physicochemical evaluation of Oral Strips

Formulation Code	Swelling Index (2h)	Content Uniformity (mg)	Thickness (mm)	Weight Variation (%)	Folding Endurance	Surface pH
F1	15.12±1.10	17.79±0.78	0.02±0.49	32.0±3.01	221.4±5.41	6.49±6.48
F2	19.00±1.09	18.00±0.12	0.13±0.22	38.0±0.00	220.5±1.31	6.55±6.54
F3	22.33±1.12	19.67±0.09	0.14±0.07	73.1±0.01	276.0±6.0	6.59±6.48
F4	26.35±1.23	20.00±0.09	0.41±0.01	196.2±0.02	168.5±3.62	6.71±6.70
F5	34.01±0.12	21.23±0.55	0.12±0.08	112.0±0.00	200±3.11	6.80±6.79

In vitro drug release

Phosphate buffer at pH 6.8 was used for *in vitro* release investigations of several formulations. The drug concentration was quantified using UV spectrophotometry at 293 nm. Results showed a rapid release profile, with 91-95% of the drug released within 5 minutes. The drug release from formulations F4 >F3 >F2 >F1 > F5 was determined to be 95.00 > 92.00 > 90.30 > 84.80 > 77.30 as described in table no 4. According to *in vitro* drug release assays, the quantity of drug released from the strip was higher when the polymer HPMC K4M used alone.

Table 4: *In-vitro* percentage drug release

Time (sec)	% drug release				
	F1	F2	F3	F4	F5
30	58.11	62.02	43.8	38.18	50.01
60	61.00	68.30	68.1	58.09	56.00
120	72.30	72.03	79.6	67.8	61.40
180	78.01	76.00	80.22	76.12	67.00
240	81.01	82.00	82.11	84.10	71.00
300	84.80	90.30	92.00	95.00	77.30

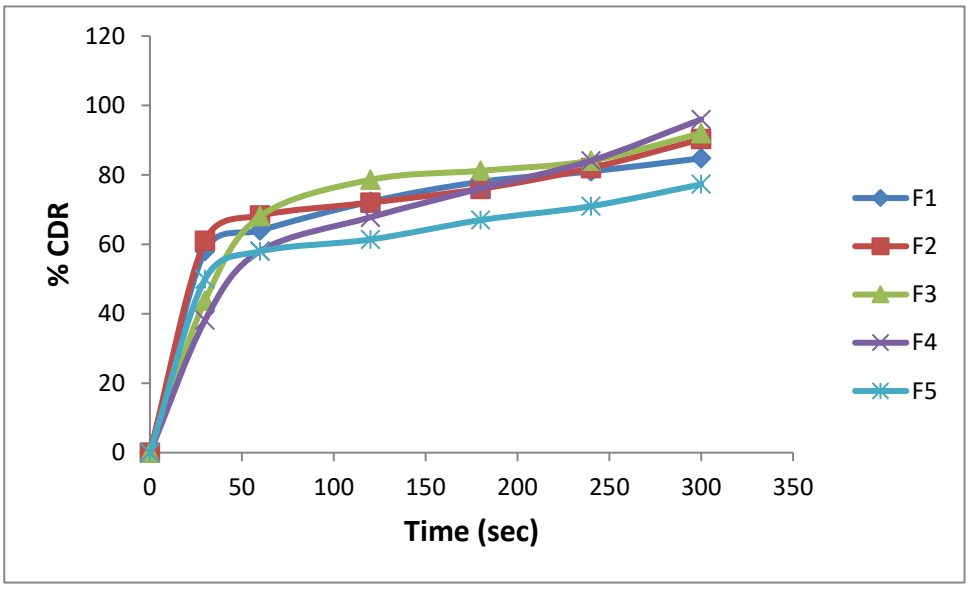

Figure 3: *In vitro* dissolution profile of ondansetron strips

Stability studies

According to the ICH recommendations, stability investigations revealed no appreciable changes in *in vitro* drug release, drug content determination, or physical appearance. The formulations were subjected to test for physical stability and pH. The formulations were stable for 3 months without any significant change in their physical appearance.

CONCLUSION

In the current investigation, an antiematic drug Ondansetron was chosen for the creation of fast dissolving oral strip based on clinical necessity. After the strips were made, they were tested for compatibility, *in vitro* release, and a number of physicochemical characteristics. All the criteria were judged to be suitable. The absence of a discernible variation in thickness across all groups suggests that the strips were consistent throughout. The strip surface appeared smooth and compact, with no apparent pores, suggesting that all formulation constituents were mixed and uniformly distributed. It was discovered that formulation factors including the polymer ratio had an impact on the *in vitro* drug release behavior, with higher polymer concentrations leading to higher *in vitro* drug release. The formulation used in the experiments F4 produced the greatest results, with a cumulative percentage of drug release of 95 % over the course of 5 minutes. The stability studies revealed that there has been no discernible change in the physical appearance, drug content determination, or *in vitro* drug release. This study's findings suggest that fast dissolving oral strip for ondansetron can be developed, prioritizing patient compliance and therapeutic efficacy.

Conflict of Interest: None

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